IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BARDY DIAGNOSTICS, INC., Plaintiff, v. IRHYTHM TECHNOLOGIES, INC., Defendant.	C.A. No. _____ **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiff, Bardy Diagnostics, Inc. ("BardyDx") files this complaint against Defendant iRhythm Technologies, Inc. ("iRhythm"), seeking damages and other relief for patent infringement, alleging as follows:

Nature of the Action

1. This is a civil action arising under the patent laws of the United States, 35 U.S.C. § 1 et seq., including specifically 35 U.S.C. § 271, seeking relief arising out of iRhythm's infringement of U.S. Patent No. 12,161,473 (the "'473 Patent").

2. BardyDx is the owner by assignment of the '473 Patent. A copy of the '473 Patent is attached as Exhibit 1.

The Parties

3. BardyDx is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 220 120th Ave NE, Suite 100, Bellevue, WA 98005.

4. Upon information and belief, iRhythm is a corporation organized and existing under the laws of the State of Delaware since September 14, 2006.

5. Upon information and belief, iRhythm has its headquarters and principal place of business at 699 8th Street, Suite 600, San Francisco, California, 94103.

6. According to iRhythm's website, iRhythm is a "digital healthcare company that creates trusted solutions that detect, predict, and prevent disease. Combining wearable biosensors and cloud-based data analytics with powerful proprietary algorithms that distill data from millions of heartbeats into clinically actionable information."

7. According to iRhythm's 2023 Form 10-K, iRhythm "offer[s] remote cardiac monitoring technology and also function[s] as [a] diagnostic service provider[]."

8. iRhythm and BardyDx are and have been competitors in the cardiac or electrocardiogram ("ECG") monitoring field.

Jurisdiction and Venue

9. This action arises under the patent laws of the United States, 35 U.S.C. § 1, et seq. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

10. Upon information and belief, as a corporation organized and existing under the laws of the State of Delaware, iRhythm has substantial and continuous contacts with Delaware and has committed acts of infringement in Delaware sufficient to confer personal jurisdiction over iRhythm.

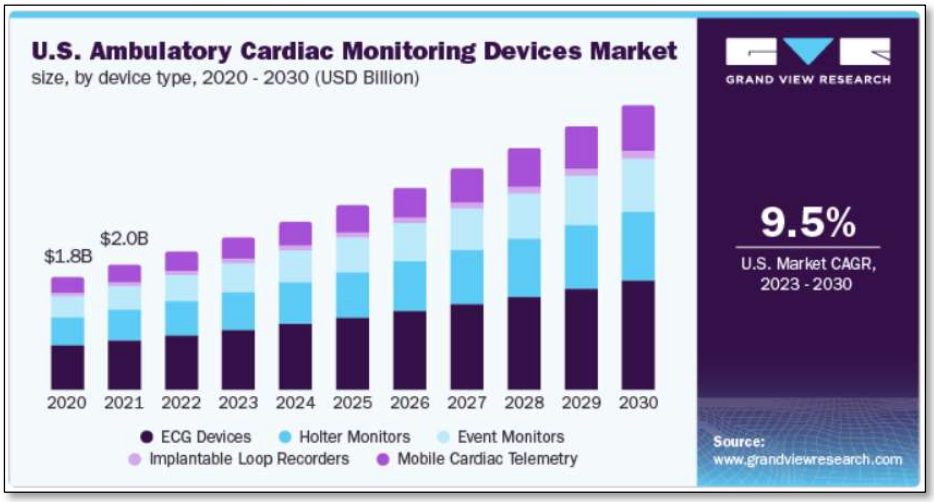
11. Upon information and belief, iRhythm is a commercial entity that makes, uses, advertises, offers for sale, and/or sells heart monitors, including but not limited to ECG monitors and ECG monitoring services. iRhythm currently manufactures, makes, uses, advertises, offers for sale, and/or sells certain ECG monitoring products, including at least the Next-Generation Zio Monitor (the "Zio Monitor").

12. Upon information and belief, iRhythm makes its Zio line of ECG monitors available to healthcare providers and patients in Delaware.

13. Venue properly lies in this Court under 28 U.S.C. §§ 1391 and 1400(b) because iRhythm, as a Delaware-incorporated corporation, resides in Delaware.

Background and Ambulatory Cardiac Monitoring Devices Market

14. The ambulatory cardiac monitoring devices market can be segmented into Holter monitors, ECG devices, event monitors, mobile cardiac telemetry, and implantable loop recorders. Ex. 2, at 1.



Id.

15. ECG devices accounted for the largest market share of 38.9% in 2022, and the demand for ECG devices is expected to continue to grow due to the increasing incidences of cardiovascular disease and hypertension worldwide, coupled with the ease of access, continuous monitoring, and high accuracy capabilities of the devices. *Id.* at 2. According to a study conducted by the World Health Organization, 17.9 million people die every year due to cardiovascular diseases, which accounts for 32% of the total deaths globally. *Id.*

16. BardyDx was founded in 2013 by an electrophysiologist and entrepreneur, Gust H. Bardy, M.D., to overcome common challenges in ambulatory cardiac monitoring. Having

witnessed firsthand his late wife's medical challenges, Dr. Bardy sought to elevate the cardiac standard of care by developing a long-term ECG monitor for identifying arrhythmias.

17. Since its founding in 2013, BardyDx has been a leading global manufacturer of cardiac monitoring solutions. For example, BardyDx manufactures, markets, and sells an industry leading electrocardiography monitor called the Carnation Ambulatory Monitor, or CAM™ Patch (shown below).

18. The CAM™ Patch is widely recognized as the first P-wave centric ECG patch monitor. This innovation was significant because P-wave analysis was traditionally performed using 12-lead ECGs. Although clinically effective, the traditional 12-lead ECG monitor had several drawbacks. Namely, the traditional 12-lead ECG monitor required patients to remain stationary due to the multiple wires or leads connected to electrodes or sensors, with the connected electrodes needing precise placement on the body for accurate readings. As a result, the

application and wear of the traditional 12-lead ECG system had to be handled carefully to avoid inaccurate and unusable results.

19. The CAM™ Patch monitor was revolutionary in that it is a P-wave centric ECG wearable monitor designed to be adhered to a patient's chest without physically restricting the patient's mobility during use. The CAM™ Patch monitor is worn on a patient's chest and continuously records ECG data for up to 14 days. The CAM™ Patch monitor is wearable during sleep, shower, and exercise.

20. Beginning on September 23, 2013, BardyDx inventors sought patent protection for these important innovations across a family of patents. This new and innovative body-worn ambulatory ECG monitor allowed physicians and healthcare providers to more effectively and efficiently monitor their patients remotely for longer periods. Not only did the patented inventions improve the quality and amount of data collected, but it also significantly reduced the cost of monitoring patients over long periods of time remotely as opposed to having the patient remain in a clinical setting during the monitoring period.

21. In addition, these patented inventions allowed for reporting of serious cardiac events, such as atrial fibrillation ("AFib"). AFib is an irregular heartbeat, or arrhythmia. It is a serious condition that can lead to blood clots, stroke, heart failure, and other heart-related complications. According to the American Heart Association, over 12 million people are projected to have AFib by 2030.

22. BardyDx has numerous U.S. and international patents that cover the innovative CAM™ Patch monitor.

23. In 2021, BardyDx was acquired by Hill-Rom Holdings, Inc. ("Hill-Rom"), a leading global medical technology company.

24. In 2017, prior to Hill-Rom's acquisition of BardyDx, Hill-Rom strengthened its focus on diagnostic cardiology and patient monitoring through its acquisition of Mortara Instrument, Inc. ("Mortara"), a leader in the field. Even earlier, in 2015, Hill-Rom acquired another leading global medical technology company, Welch Allyn, Inc. ("Welch Allyn").

25. The 2021 acquisition of BardyDx brings together the innovative research and development teams of Mortara and Welch Allyn with BardyDx.

26. Today, BardyDx continues to be a leading global manufacturer of physical examination instruments and accessories and electronic medical record connected vital sign and cardiac monitoring solutions through its manufacturing, marketing, and selling of the CAM™ Patch monitor, a leading remote cardiac monitoring solution.

The '473 Patent

27. BardyDx is the assignee of the entire right, title, and interest in numerous United States patents, including the '473 Patent.

28. The '473 Patent is titled "Electrocardiography Patch" and was duly and legally issued on December 10, 2024, and is assigned to BardyDx.

29. The '473 Patent claims, among other things, an electrocardiography monitor patch.

iRhythm

30. iRhythm was founded by Uday Kumar in 2006, and currently iRhythm makes, uses, advertises, offers for sale, and/or sells various ECG monitoring products, including the Zio Monitor. *See* Ex. 3.

31. According to iRhythm's website, iRhythm's technology "combin[es] wearable biosensors and cloud-based data analytics with powerful proprietary algorithms, [and] distills data from millions of heartbeats into clinically actionable information."

32. In addition to the Zio Monitor, iRhythm offers two other ECG monitoring products, including the Zio XT Monitor and the Zio AT Monitor.

33. iRhythm's Zio XT Monitor was cleared by the FDA under Section 510(k) of the Federal Food, Drug and Cosmetic Act on July 18, 2012. *See* Ex. 4. The Zio XT Monitor was originally called the Zio Patch, but iRhythm rebranded the Zio Patch as the Zio XT Monitor. *Compare id.*, *with* Ex. 5, at 5.

34. iRhythm's Zio AT Monitor was cleared by the FDA under Section 510(k) of the Federal Food, Drug and Cosmetic Act on June 2, 2017. *See* Ex. 6. The Zio AT Monitor was originally called the Zio QX Monitor, but iRhythm rebranded the Zio QX Monitor as the Zio AT Monitor. *Compare id.*, *with* Ex. 7, at 20.

35. iRhythm's Zio Monitor was cleared by the FDA under Section 510(k) of the Federal Food, Drug and Cosmetic Act on May 21, 2021. *See* Ex. 4.

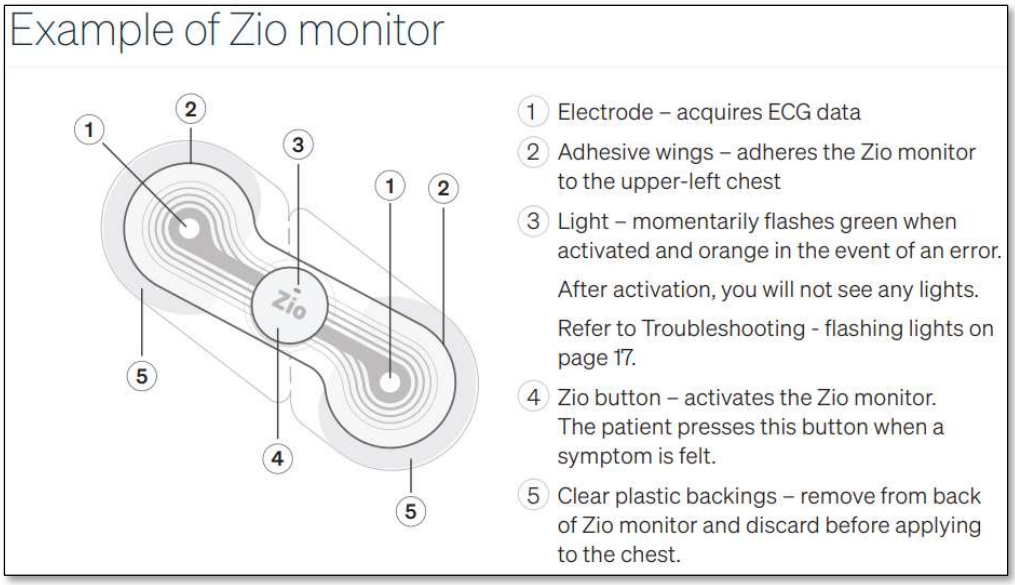
iRhythm's Next-Generation Zio Monitor

36. The Zio Monitor (also referred to as the "Next-Generation Zio Monitor") is similar to iRhythm's Zio AT and Zio XT Monitors but has an improved form factor, "which is 23% thinner, 62% lighter, and 72% smaller." Ex. 8, at 2; *see also* Ex. 9. iRhythm's Chief Technology Officer explained that "miniaturization was focused on very clever ways of handling some of the larger components, which for example involved moving some of the big resistors that are required on the device to the more flexible part of the patch instead of on the actual printed circuit board in the housing" by "integrat[ing] [the resistors] into the ECG tracings themselves." Ex. 8, at 3.

37. iRhythm promotes and markets the Zio Monitor on its website. A screenshot of the Zio Monitor from iRhythm's website is copied below.

Ex. 3.

38. The Zio Monitor includes adhesive portions for adhering to a patient's chest to "capture symptomatic and asymptomatic cardiac events in a continuous electrocardiogram record for long-term monitoring." Ex. 10, at 21. The electrocardiographic data is acquired by two electrodes provided on each end of the Zio Monitor. *Id.* at 3.

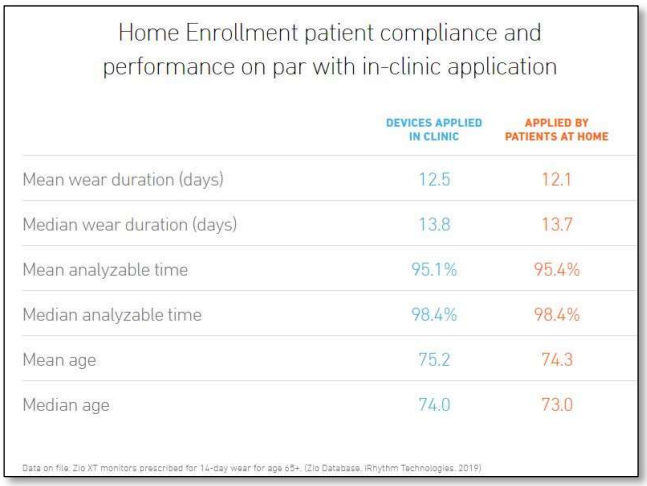


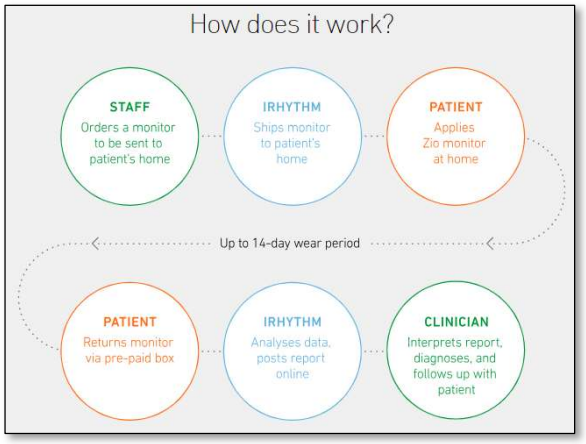
Id.

39. The Zio Monitor senses and records the ECG data continuously for up to 14 days. *Id.* at 6. After conclusion of the wear period (up to 14 days), the patient removes the Zio Monitor

and returns it by mail to an iRhythm data processing center. *Id.* at 2. Upon iRhythm's receipt the ECG data is further processed, and a report is generated. *Id.*

40. iRhythm makes the Zio Monitor available to patients directly or through healthcare providers. Ex. 11, at 2.





Id. at 2–3.

41. Upon information and belief, iRhythm manufactures the Zio Monitor in the U.S.

42. iRhythm plans to release its Zio MCT monitor, which "will be on the same form factor that Zio Monitor is on currently. . . . With [Zio] MCT and [Zio] Monitor, they will be the same exact product and manufactured on a single line." Ex. 12, at 10. iRhythm intends for the 9

43. iRhythm intends to commercially launch its Zio MCT monitor in 2027 or 2028. *Id.* at 11.

COUNT I

Patent Infringement of U.S. Patent No. 12,161,473

44. BardyDx realleges and incorporates by reference the allegations in paragraphs 1–43 of this Complaint.

45. iRhythm makes, uses, sells, and/or offers for sale the Zio Monitor in the United States. Any of these individual activities is an act of infringement under 35 U.S.C. § 271(a), and,

as set forth in the attached non-limiting Claim Chart (Ex. 13), iRhythm directly infringes at least claims 1–3, 6, 8, 10, 13, 15, 16, and 19 of the '473 Patent, either literally or under the doctrine of equivalents.

46. iRhythm has engaged in the foregoing conduct with respect to the patented invention in the United States without authority from BardyDx and during the term of the '473 Patent.

47. Thus, iRhythm is liable to BardyDx in an amount that compensates it for such infringement, which by law cannot be less than a reasonable royalty, together with interest and costs as fixed by this Court under 35 U.S.C. § 284.

RELIEF REQUESTED

WHEREFORE, BardyDx requests that the Court enter a judgment in its favor and against iRhythm and provide BardyDx the following relief:

A. Order, adjudge, and decree that iRhythm has infringed the '473 Patent;

B. Order, adjudge, and decree that iRhythm's infringement of the '473 Patent is exceptional under 35 U.S.C. § 285;

C. Award BardyDx damages for patent infringement including prejudgment interest and costs against iRhythm under 35 U.S.C. §§ 284 and 289;

D. Award BardyDx up to three times its damages to compensate BardyDx under 35 U.S.C. § 284;

E. Award BardyDx its reasonable attorneys' fees under 35 U.S.C. § 285; and

F. Award such other and further relief as the Court may deem just including but not limited to an accounting for acts of infringement made but not otherwise awarded to BardyDx.

JURY DEMAND

BardyDx demands trial by jury on all issues presented in this complaint.

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Dated: December 10, 2024
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